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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,252	08/02/2006	Richard F. Labaudiniere	118410-00301	9703
86738 7590 09/23/2010 MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110				
EXAMINER JAVANMARD, SAHAR				
ART UNIT 1627		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,252

Applicant(s)

LABAUDINIERE ET AL.

Examiner

SAHAR JAVANMARD

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9, 23, 24, 29, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 29, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on September 8, 2010. Claim(s) 1-4, 9, 23, 24, 29, 43 and 44 are pending. Claim(s) 1-4 and 9 are withdrawn. Claim(s) 23, 24, 29, 43 and 44 are examined herein.

Response to Arguments

In view of Applicants amendments, the 102(e) rejection of claims 23, 24, and 27-29 as being anticipated by Suto (US Pub. No. 2004/0180889) is hereby withdrawn.

Applicants arguments with respect to the 103(a) rejection of claims 23, 24, and 27-29 as being unpatentable over Gerlach (US Patent No. 6,699,877B2) of record have been fully considered but are not persuasive with the exception of cancelled claims 27 and 29. Applicant argues:

"Applicants note that Gerlach does not teach or suggest the compounds in the genus of claim 23, and further fails to teach or suggest the specific compounds set forth in claim 29."

Applicant further argues:

"Applicants respectfully submit that there is nothing in Gerlach to suggest to one of skill in the art to select any compound disclosed in Gerlach out of the numerous compounds disclosed, as the best performing compound, and therefore, a target for

further modification to improve properties. Comparable to Takeda, Gerlach discloses a broad number of compounds without identifying any predictable solutions to enhance biological activity, efficacy or safety of such compounds, and any one of the broad number of compounds disclosed in this patent could have been selected for further modification. Moreover, Gerlach does not provide any suggestion or motivation to select any compound disclosed within it for further modification."

With respect to these arguments, Examiner respectfully notes that in fact Gerlach does encompass the compounds of the instant invention as set forth on the record in the previous Office action. Moreover, there is no reason to modify the reference as Applicant suggests. As noted previously, Gerlach teaches compounds of formula I wherein R1 and R2 together form an unsaturated cyclopentane ring to yield the cycloalkyltetrahydroquinoline backbone as taught by the instant invention (see claim 1). Examiner notes that, as taught by Gerlach, the possible variations of R1 and R2 together is less than approximately 20, therefore arriving at the compounds wherein R1 and R2 together form an unsaturated cyclopentane ring is not considered to be as "numerous" as suggested by Applicant. Thus based on reasons of record, the instant rejection is hereby maintained.

The Office action below is made Final as necessitated by amendment.

Objections

Claims 1 and 9 have incorrect claim status identifiers. Appropriate action is required.

For sake of consistency, the carboxyl moiety of the compounds in claim 44 should be drawn as recited in claims 23 and 29. Appropriate action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 recites compound XX. There is insufficient antecedent basis for this compound in the claim. R1-R4 cannot be C(O)OR, therefore the CO₂Me substituent on the phenyl ring does not have antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 24, 29, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerlach (US Patent No. 6,699,877B2) of record.

Gerlach teaches 1,2,3,4-tetrahydroquinoline-2-carboxylic acid derivatives of formula I, wherein R1 and R2 together form an unsaturated cyclopentane ring; R3 is H; R4 is H; R5-R8 are R5, R6, R7 and R8, independently of one another, are H, F, Cl, Br, I, CN, NO₂; respectively branched or unbranched, singly or multiply substituted or unsubstituted C1-C10 alkyl, C2-C10 alkenyl or C2-C10 alkynyl; OR14, OC(O)R14, OC(S)R14, C(O)R14, C(O)OR14, C(S)R14, C(S)OR14, SR14, S(O)R14 or S(O₂)R14, wherein R14 is H; respectively branched or unbranched, singly or multiply substituted or unsubstituted C1-C10 alkyl, C2-C10 alkenyl or C2-C10 alkynyl; saturated or unsaturated, singly or multiply substituted or unsubstituted C3-C8 cycloalkyl, or a corresponding heterocycle, in which at least one carbon atom in the ring is replaced by S, O or N; respectively singly or multiply substituted or unsubstituted alkyl aryl or alkyl heteroaryl; respectively singly or multiply substituted or unsubstituted aryl or heteroaryl; NR15R16, NR15C(O)R16, C(NR15)NR16R17, NR15C(S)R16, C(S)NR15R16 or C(S)NR15NR16R17 or S(O₂)NR15R16, wherein R15, R16 and R17, independently of one another, are H, O; respectively branched or unbranched, singly or multiply substituted or unsubstituted C1-C18 alkyl, C2-C18 alkenyl or C2-C18 alkynyl; saturated

or unsaturated, singly or multiply substituted or unsubstituted C3-C8 cycloalkyl, or a corresponding heterocycle, in which at least one carbon atom in the ring is replaced by S, O or N, respectively singly or multiply substituted or unsubstituted alkyl aryl or alkyl heteroaryl; or respectively singly or multiply substituted or unsubstituted aryl or heteroaryl; or R15 and R16 or R16 and R17 together form a saturated or unsaturated, singly or multiply substituted or unsubstituted C3-C8 cycloalkyl, or a corresponding heterocycle in which at least one carbon atom in the ring is replaced by S, O or N; or R5 and R6, R6 and R7 or R7 and R8 together form CR18CHCHCH or CHCR18CHCH, wherein R18 is H, F, Cl, Br, I, OH or respectively branched or unbranched, singly or multiply substituted or unsubstituted C1-C10 alkyl, C2-C10 alkenyl or C2-C10 alkynyl; provided that if R1 and R2 together form CHCHCH2 or R3 is (j)p-menthan-3-ol, and R7Cl, then R5, R6 and R8 are not simultaneously H, if R1 and R2 together form CHCHCH2, R3 is CH3, and R7 is H, Cl or OCH3, then R5, R6 and R8 are not simultaneously H, if R1 and R2 together form CHCHCH2, R3 is H, and if R7 is OCH3 or C(O)NH2, then R5, R6 and R8 are not simultaneously H, if R5R7CH3, then R6 and R8 are not simultaneously H, if R5OCH3, then R6, R7 and R8 are not simultaneously H, and if R1 and R2 together form or OCH2CH2 and R3 is C2H5 and if R7 is H, Cl, CH3, OCH3 or NO2, then R5, R6 and R8 are not simultaneously H, and if R5NO2; then R6, R7 and R8 are not simultaneously H (column 2-column 4; claim 1).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Coming Glass Works v.*

Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". *KSR v. Teleflex*, 127 S. Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Ida*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S. Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various substituents from within a prior art disclosure, to arrive at the compounds that are encompassed by the compounds of formula I-a'.

Therefore, based on reasons of record, the claims 23, 24, 29, and 43-44 are deemed unpatentable over the cited art.

Claims 23, 24, 29, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes (US Patent No. 5,925,527) of record.

Hayes teaches compounds of formula I which encompass the compounds of the instant invention wherein R1 is absent; Y is CO₂H, NHR7, C(O)NHR7, wherein R7 is H, C1 to C10 alkyl; R2-R4 are independently H; R5 is a carboxy; R6 is H; and n is 1 to 3 (column 3, line 15-column 4, line 53).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". *KSR v. Teleflex*, 127 S. Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Ida*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not

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Consistent with this reasoning, it would have obvious to have selected various combinations of various substituents from within a prior art disclosure, to arrive at the compounds that are encompassed by the compounds of formula I-a'.

Therefore, based on reasons of record, the claims 23, 24, 29, and 43-44 are deemed unpatentable over the cited art.

Conclusion

Claims 23, 24, 29, and 43-44 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1627